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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/831,272	08/13/2001	Christoph Kirsch	4038.001	3234
41288	7590	09/12/2006	EXAMINER	
STEPHAN A. PENDORF, P.A. PENDORF & CUTLIFF 5111 MEMORIAL HIGHWAY TAMPA, FL 33634			MARVICH, MARIA	
			ART UNIT	PAPER NUMBER
			1633	

DATE MAILED: 09/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/831,272	KIRSCH ET AL.	
	Examiner	Art Unit	
	Maria B. Marvich, PhD	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 May 2005 and 28 September 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-40 and 42-46 is/are pending in the application.
- 4a) Of the above claim(s) 1,4-7,10-21,23-38,40 and 46 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2,8,9,22,39 and 42-45 is/are rejected.
- 7) ☒ Claim(s) 3 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 31 January 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This office action is in response to an amendment filed 6/27/06. Claim 41 has been cancelled. Claims 1-40 and 42-46 are pending in the application. Claims 1, 4-7, 10-21, 22-38, 40 and 46 have been withdrawn. Therefore, claims 2, 3, 8, 9, 22, 39 and 42-45 are under examination. Claims 2, 22 and 42 have been amended.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/27/06 has been entered.

Claim Objections

Claim 2 is objected to because of the following informalities: while SEQ ID NO:11 appears to be of the “two or more cis-acting elements”, by recitation of “a cis-acting element, this relationship is not indicated. It would be remedial to delete “a cis-acting elicitor responsive element consists of” and replace it with -- at least one of the two or more cis-acting elements is--.

While claim 22 is drawn to a cis-acting element that consists of SEQ ID NO:11. While the cis-element consists of SEQ ID NO:11, the claim does not recite that the cis-acting element is isolated from its natural source or not part of a more complex promoter. It would be remedial to recite that the element is -- isolated -- to remove any ambiguity.

These are new rejections. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 9 and 42-45 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 9 recites the limitation "said multimeric forms" in claim 2. There is insufficient antecedent basis for this limitation in the claim. **This is a new rejection.**

Claim 42 recites the limitation "said at least one cis-acting element" in claim 2. There is insufficient antecedent basis for this limitation in the claim. **This rejection is maintained for reasons of record in the office action mailed 12/27/05.**

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 2, 8 and 39 are rejected under 35 U.S.C. 102(b) as being anticipated by van de Locht et al (EMBO J, 1990, vol 9(9) p 2945-2950; see entire document). **This rejection is maintained for reasons of record in the office action mailed 7/28/04 and 12/27/05 and restated below. Upon reconsideration, the rejection has been extended to claim 39.**

Van de Locht et al teach a promoter obtainable by insertion of pPR2-10, which comprises at least one cis-acting element sufficient to direct elicitor-specific expression into the promoter of the GUS reporter gene as recited in claim 39. pPR2-10 comprises SEQ ID NO:11 as indicated in figure 5 which demonstrates that pPR2-10 comprises the region from -168 to -43. This region comprises SEQ ID NO:11 and functions as a cis-element sufficient to direct elicitor specific expression with the CAAT element. Hence the vector comprises at least two-cis acting elements.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2, 8 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over van de Locht et al (EMBO J, 1990, vol 9(9) p 2945-2950; see entire document) in view of Pears and Williams (Nucleic Acids Research, 1988, Vol 16(17), pages 8467-84861; see entire document) and Searle et al, MCB, 1985, Vol 5(6), pages 1480-1489; see entire document) further in view of Comai et al (Plant Molecular Biology, 1990, Vol 15(3), pages 373-381; see entire document). **This rejection is maintained for reasons of record in the office action mailed 7/28/04 and 12/27/05 and restated below. Upon reconsideration, the rejection has been extended to claims 8 and 39.**

Applicants claim a chimeric promoter comprising two or more cis-acting elements comprising SEQ ID NO:11. This rejection is directed to an alternative reading of the claim that the promoter comprises at least two copies of SEQ ID NO:11.

The teachings of van de Locht et al are described above and are applied as before except; van de Locht et al do not teach that pPR2-10 comprises two copies of the elicitor element.

Pears and Williams teach that heterologous promoter sequences inserted into promoters can mediate sufficient gene expression (see e.g. abstract). Specifically, Pears and Williams teach that the promoter elements function “optimally” when multiple copies of the sequences are present (see e.g. page 8480 and figure 7).

Searle et al teach that promoters comprising two heterologous inducible elements isolated from the methallothionein I gene function as strong inducible promoter, whereas a single element did not respond to zinc (see e.g. abstract). Applicants reason that more than two should further increase the inducibility of the promoter.

Comai et al teach that promoters can be duplicated with the effect of enhanced expression (see e.g. abstract).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to duplicate the isolated promoter fragment that is elicitor responsive as taught by van de Locht et al as taught by Pears and Williams and Searle et al and Comai et al because and van de Locht et al teach that a fragment of the PR2 promoter is responsible for strong elicitor mediated gene activation and because Pears and Williams and Searle et al teach that multiple elements are more effective than single elements and Comai et al teach that it is within the

Art Unit: 1633

ordinary skill of the art to generate chimeric vectors in which larger promoter elements are duplicated. One would have been motivated to do so in order to receive the expected benefit of enhanced regulation of heterologous genes. Based upon the teachings of the cited references, the high skill of one of ordinary skill in the art, and absent evidence to the contrary, there would have been a reasonable expectation of success to result in the claimed invention.

Response to Argument

Applicants traverse the claim rejections under 35 U.S.C. 102 and 103 on pages 10-12 of the amendment filed 6/27/06. Applicants argue that van de Loch et al do not teach a **chimeric** promoter comprising SEQ ID NO:11 and a minimal promoter comprising two or more cis-acting elements wherein a cis-acting elicitor responsive element comprises a nucleotide sequence of SEQ ID NO:11. Furthermore, applicants argue that it would not have been obvious to identify the actual fragment that is the elicitor-specific responsive element. Finally, applicants argue that Pears and Williams, Searle et al and Comai et al do not teach the same elicitor responsive elements and do not cure the deficiencies of Loch et al.

Applicants' arguments filed 1/31/05 have been fully considered but they are not persuasive. The promoter of van de Loch et al as disclosed in Figure 5 and 6 is a chimeric promoter formed by fusion of parsley chalcone synthase promoter (which provides the minimal promoter) to a PR2 fragment. The cis element within the promoter consists of SEQ ID NO:11. The promoter directs high levels of elicitor dependent GUS activity (see e.g. figure 6). Hence, the promoter of van de Loch et al does anticipate the instant claims. Pears and Williams, Searle et al and Comai need not teach what the primary reference teaches. The teachings of van de Loch et al disclose a chimeric promoter comprising a cis-element that consists of SEQ Id

Art Unit: 1633

NO:11. The teachings of Pears and Williams, Searle et al and Comai are provided simply to teach that duplication of promoter elements are well known in the art and provide a desired benefit that would have made obvious duplication of the cis element of van de Locht et al to generate a more efficient and powerful promoter.

Conclusion

Claim 3 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

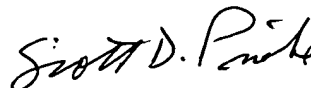
Claims 2, 8, 9, 22, 39 and 42-45 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria B. Marvich, PhD whose telephone number is (571)-272-0774. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Nguyen, PhD can be reached on (571)-272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maria B Marvich, PhD
Examiner
Art Unit 1633



SCOTT D. PRIEBE, PH.D
PRIMARY EXAMINER